CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

September 27, 2002

H.R. 4014
Rare Diseases Orphan Product Development Act of 2002

As ordered reported by the House Committee on Energy and Commerce on September 5, 2002

SUMMARY

H.R. 4014 would authorize funding for an existing grant program administered by the Food and Drug Administration (FDA) that sponsors clinical testing of the safety and effectiveness of new products to treat or diagnose rare diseases.

The bill would authorize the appropriation of $25 million a year for fiscal years 2003 through 2006. CBO estimates that implementing H.R. 4014 would cost $8 million in 2003 and $93 million over the 2003-2007 period, assuming the appropriation of the authorized amounts. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 4014 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). State, local, and tribal governments could enter into contracts and receive grants authorized by the bill, and any costs they incur would be voluntary.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 4014 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2002	2003	2004	2005	2006	2007
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Authorization Level	0	25	25	25	25	0
Estimated Outlays	0	8	21	23	24	17

BASIS OF ESTIMATE

H.R. 4014 would authorize funding for an existing grant program administered by the FDA that sponsors clinical studies on the safety and effectiveness of new products to treat or diagnose rare diseases. The amount appropriated for fiscal year 2002 for the current program is $13 million. The bill would authorize the appropriation of such sums as already have been appropriated for fiscal year 2002, and $25 million for each of the fiscal years 2003 through 2006.

Research grants awarded under the program would defray some of the costs associated with clinical testing of certain orphan drugs, biologicals, medical devices, and medical foods. An orphan drug is a drug or biological that is used to treat or diagnose an illness usually affecting fewer than 200,000 people in the United States. Eligible medical devices and medical foods include products for which there is no reasonable expectation of development without grant assistance because the condition occurs relatively infrequently in the United States.

CBO estimates that implementing H.R. 4014 would cost $8 million in 2003 and $93 million over the 2003-2007 period, assuming appropriation of the necessary amounts. This estimate incorporates general spending patterns for research grant programs administered within the Public Health Service.

PAY-AS-YOU-GO CONSIDERATIONS: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 4014 contains no intergovernmental mandates as defined in UMRA. State, local, and tribal governments enter into contracts and receive grants authorized by the bill, and any costs they incur would be voluntary.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains no private-sector mandates as defined in UMRA.

PREVIOUS ESTIMATE

On December 5, 2001, CBO transmitted a cost estimate for S. 1379, the Rare Diseases Act of 2001, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on November 1, 2001. S. 1379 contains a provision very similar to H.R. 4014 that funds FDA's grant program for the development of orphan products. The main difference between the provision in the two bills is that S. 1379 would authorize the appropriation of $25 million in 2002 and such sums as necessary for each subsequent year while H.R. 4014 would authorize such sums as already have been appropriated for fiscal year 2002, and $25 million in funding each year from 2003 through 2006.

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